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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/780,444

02/17/2004

Peter M. Bonutti

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SUITE 115

MIAMI, FL 33180

EXAMINER

SZPIRA, JULIE ANN

ART UNIT

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/780,444	Applicant(s) BONUTTI ET AL.	
	Examiner JULIE A. SZPIRA	Art Unit 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 April 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 and 49-57 is/are pending in the application.
- 4a) Of the above claim(s) 9-17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8, 18-24 and 49-57 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4/23/2009 has been entered.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 49 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
3. Claim 49 recites the limitation "suture" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

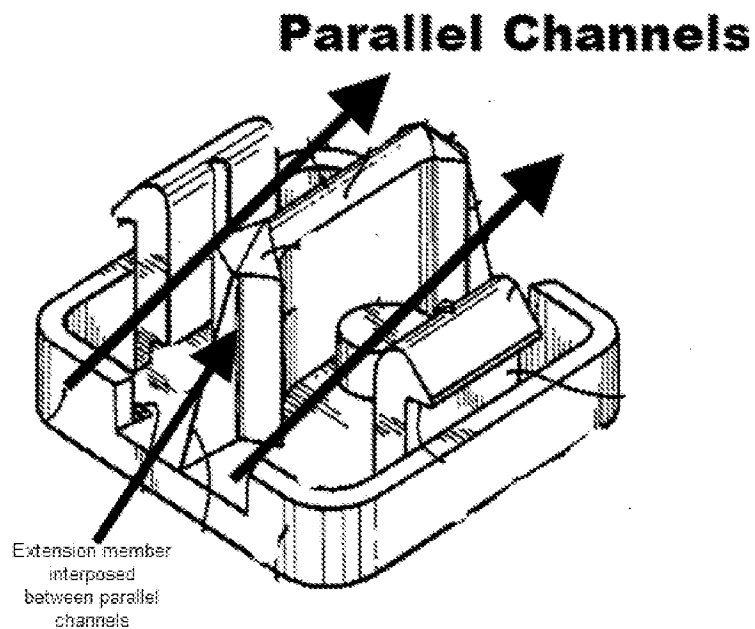
5. **Claims 1-8, 19, 24 and 50-53** are rejected under 35 U.S.C. 102(b) as being anticipated by **Merritt (US 5,208,950)**.

Regarding claim 1, Merritt discloses a device that is capable being implanted and securing an object relative to a body tissue (cord lock, 10) comprising a first (male body, 14) section including a first surface (54) and an extension member (projection, 66) extending from that surface, and a second (female body, 12) section including a second surface (34) opposing the first surface and being configured for receiving the extension member (recess, 35), the first and second section being bondable together with the application of an energy source (ultrasonic welding; column 4, lines 35-36).

Regarding claim 2, Merritt discloses an object (cord) interposed between the first and second sections (column 3, lines 15-18).

Regarding claim 3, Merritt discloses the first and second section bonded (snap-locked) together to secure the object (column 4, lines 13-20).

Regarding claim 4, Merritt discloses the first section including a pair of parallel channels (Figure 4, see below).



Regarding claim 5, Merritt discloses the extension member (66) interposed between the pair of parallel channels (Figure 4, see above).

Regarding claim 6, Merritt discloses the second section including a channel (recess, 35) configured for receiving the extension member (column 3, lines 56-59).

Regarding claim 7, Merritt discloses the object (cord) including a first (19) and second (21) end, one each positionable within the parallel channels (column 3, lines 62-64; Figure 1).

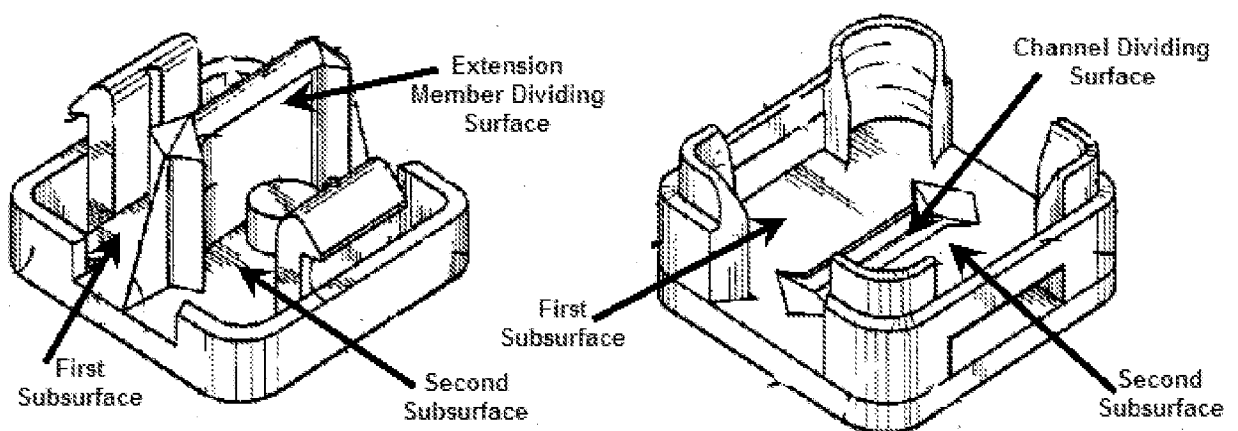
Regarding claim 8, Merritt discloses the suture interposed between the first and second sections when the extension member is positioned within the channel (column 4, lines 16-20).

Regarding claim 19, Merritt discloses the first and second sections interconnected by a system of pins and recesses (column 4, lines 11-16).

Regarding claim 24, Merritt discloses the energy source being ultrasonic energy (welding) (column 4, lines 33-36).

Regarding claim 50, Merritt discloses the first section has two channels (76) formed therein, said channels being disposed opposingly about and immediately adjacent to said extension member and the second section is configured to seat within the channels of the first section (Figure 3).

Regarding claim 51, Merritt discloses said extension member divides said first surface into a first first-surface subsurface and a second first-surface subsurface, a channel divides said second surface into a first second-surface subsurface and a second - surface subsurface (See Figure Below), said first first-surface subsurface is configured to align with said first second-surface subsurface when said first section is bonded to said second section; and said second first-surface subsurface is configured to align with said second second-surface subsurface when said first section is bonded to said second section (Figure 3)

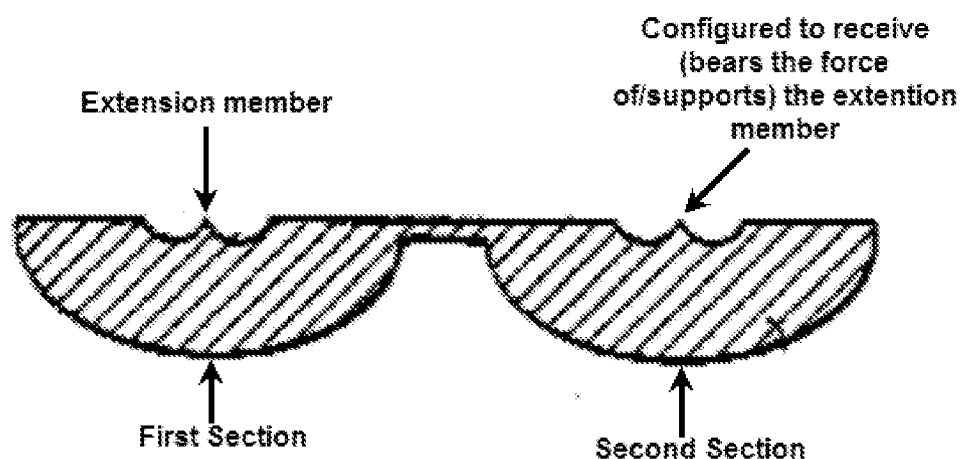


Regarding claim 52, Merritt discloses an object (cord) sandwiched between a first first-surface subspace and said first second-surface subspace and a second first-surface subspace and said second second-surface subspace (Figure 1).

Regarding claim 53, Merritt discloses the object being elongated (cord, 10; Figure 1).

6. **Claims 1, 18, 49 and 54** are rejected under 35 U.S.C. 102(b) as being anticipated by **Egan (US 6,174,324)**.

Regarding claim 1, Egan discloses a device that is capable being implanted and securing an object relative to a body tissue comprising a first section including a first surface and an extension member extending from that surface, and a second section including a second surface opposing the first surface and being configured for receiving the extension member (See Figure Below) the first and second section being bondable together with the application of an energy source (ultrasonic energy; column 5, lines 23-37).



Regarding claim 18, Egan discloses the first and second sections being textured to enhance the retention and tension of the suture strands within the device (column 4, lines 47-51).

Regarding claim 49, Egan et al. discloses the first and second surfaces configured to sandwich the suture (Figure 12).

Regarding claim 54, Egan et al. discloses a suture (104).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. **Claim 20** is rejected under 35 U.S.C. 103(a) as being unpatentable over **Egan (US 6,174,324)** in view of **Hart (US 5,630,824)**.

Regarding claim 20, Egan discloses the invention substantially as claimed above, but fails to disclose the suture retainer made of a biodegradable material.

However, Hart teaches a suture retainer (attachment device) made of a biodegradable polymer (column 4, lines 50-52).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to create the suture holder out of a biodegradable material so the device can dissolve after the wound which the suture is attached to heals (column 4, lines 52-65).

10. **Claim 21** is rejected under 35 U.S.C. 103(a) as being unpatentable over **Merritt (US 5,208,950)** in view of **Tokushige et al. (US 5,866,634)**

Regarding claim 21, Merritt discloses the invention substantially as claimed above, but fails to disclose the suture retainer made of heat shrink material.

However, Tokushige et al. teaches a biodegradable shrink material that has superior strength, flexibility, and the ability to shrink at lower temperatures (column 1, lines 39-42; column 4, lines 19-22).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to create the suture holder out of a heat shrink material because it would allow the suture retainer to shrink around the suture (container) with minimal warping (column 3, lines 24-26).

11. **Claims 22 and 23** are rejected under 35 U.S.C. 103(a) as being unpatentable over **Egan (US 6,174,324)** in view of **Bartlett (US 5,879,372)**.

Regarding claims 22 and 23, Egan discloses the invention substantially as claimed above, but fails to disclose the suture retainer including viable cells or pharmaceutical agents.

However, Bartlett teaches the suture retainer (anchor) including viable cells (bone tissue) and pharmaceutical agent (hydroxyapatite) (column 4, lines 34-36 and 46-50).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to include viable cells and a pharmaceutical agent to strengthen the area in which the device is placed (column 4, lines 24-26).

12. **Claims 55-57** are rejected under 35 U.S.C. 103(a) as being unpatentable over **Egan (US 6,174,324)**.

Regarding claims 55-57, Egan discloses the invention substantially as claimed above, but fails to disclose the object being body tissue or metallic.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the object body tissue or metallic, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. In re Leshin, 125 USPQ 416.

Furthermore, the device as claimed is capable of securing a variety of material and it has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. Ex Parte Masham, 2 USPQ F.2d 1647 (1987).

Response to Arguments

13. Applicant's arguments have been considered but are moot in view of the new ground(s) of rejection.

14. In this case, the device disclosed by Merritt is structurally similar to many suture anchors well known in the art. The application of a cord retainer as a suture retainer is well within the knowledge of one having ordinary skill in the art. The decision to make the device disclosed by Merritt from a variety of different materials suitable for a suture anchor, such as a biodegradable material or a heat shrink material would have been obvious to one having ordinary skill in the art.

The intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. The devices disclosed by Merritt and Egan have the capability of performing the intended use. The current claims do not positively recite the fastener being implanted in a body, and only claims "an implantable fastener" meaning that any place of implantation (within an elastic netting, in a machine or any other place) that places the fastener relative to the body would meet the claim. The term "relative" also has a very open meaning. As long as a relative term (i.e. near, far, left, right, up, down) is used to describe the relationship of the fastener to the body, the claim limitations are met.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JULIE A. SZPIRA whose telephone number is (571) 270-3866. The examiner can normally be reached on Monday-Thursday 9 AM to 6 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Julie A Szpira/
Examiner, Art Unit 3731

/Anhtuan T. Nguyen/
Supervisory Patent Examiner, Art Unit 3731
7/3/09